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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,466	06/20/2001	Arthur L. Herbst	58532-012	9630

20277 7590 11/06/2003

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	16

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,466	Applicant(s) HERBST ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-26* is/are pending in the application.

4a) Of the above claim(s) *16 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/14/2003 has been entered.

Status of application

Acknowledgement is made of amendment filed 08/14/03. As requested, the claims 1-12 are canceled and the claims 13-26 are newly added.

The claims 13-26 are pending.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: fatigue, diarrhea, rectal bleeding, urinary frequency, dysuria or nocturia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim1 is generic.

As evidenced by numerous US patents, each claimed species is patentably distinct from others. For instance, US6403640 teaches a treatment of prostatitis using COX-2 inhibitor. US 2001/0011097 teaches a treatment of mucositis using COX-2.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Price, Robert a provisional election was made to prosecute thepatentably distinct species, fatigue that is recited in claims 13-15, 17 and 23-26. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 16, 18-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 13-15, 17 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (US 6096728) in view of Kutilek, III et al(US 5,770,217) ,Wilder (US 2002/0009421), Bull et al(US5506145), Shafran (US 6,297,015) and .

Collins et al (US'728 hereafter) teaches a composition comprising COX2 inhibitor such as celecoxib used in the treatment of acute or chronic inflammatory diseases including chronic fatigue syndrome or side effects from radiation therapy, see column 1, line 57, column 2, line 3 and column 32, lines 21-34.

Although US'728 does not specifically teach the fatigue as the specific species of said side effects(US'728) from radiation therapy, it would have been , however, obvious to one of ordinary skill in the art to extend the teaching of US'728 at the time of the invention was made to apply not only to chronic fatigue syndrome but also to fatigue that is a side effect induced by radiation when Collins et al is modified with Wilder, Bull and Shoran's teaching because each patentee teaches a piece of information that remedies the deficiency of US'728.

It is commonly known to any skilled artisan that fatigue is mediated by inflammatory process and also induced by raditation exposure known as a common side effect from radiation therapy.

The said conventional knowledge is as evidenced by numerous prior art references including applicants own admission (see instant specification at page 4, paragraph 19 and see also references in PTO-892 enclosed).

For instance, Kutilek, III et al(US'217 hereafter) teaches a fatigue is a side effect that is so commonly associated with radiation/chemo-therapy, see column 16, lines 39-43 and column 3, lines 56-63. Although the invention of US'217 is not relevant to the instant invention, it is cited because it has the literal support on the allegation this examiner made. Bull et al(US'145 hereafter) teaches that fatigue, fever chills are signs and symptoms of inflammation wherein the treatment of said signs and symptoms can be corrected by treating inflammation, see column 1,lines 32-45.

Meanwhile, Wilder et al(US421) and Shafran et al(US'015) teaches the effectivenss of COX-2 inhibitors and its use in the treatment against not only radiation induced inflammation but also fatigue or other symptoms and signs such as fever and chills as well.

Wilder et al (US'421, hereafter) teaches an effective treatment of UV radiation induced photodamages to the skin and symptoms related thereto such as inflammation, weakness, chills, fever, pain and tenderness, using a therapeutically effective amount of COX-2 inhibitors such as celecoxib or rofecoxib, see full text, especially paragraphs 28-31 at column 4. The effective dosage regimen for the topical application of COX-2

inhibitor is about 50-400mg per unit dosage, preferably 100-200mg in suspension or solution, see paragraphs 34-35 at column 4.

Shafran et al (US'015 hereafter) teaches a COX-2 inhibitor such as celecoxib and its use in the treatment of side effects such as fatigue, fever, and chills associated with rifabutin and macrolide(e.g. clarithromycin) antibiotic therapy(RMAT) used in treating crohn's disease, see column 5, lines 60 thru column 6, lines 18. US'015 teaches that the symptoms(e.g. fatigue) is responded well to COX-2 inhibitor such as celecoxib with 200mg /per day with no adverse effects.

Thus, it would have been obvious to one of ordinary skill in the art to use COX-2 inhibitors to treat radiation induced fatigue when these references are combined because the successful result for the treatment of radiation induced fatigue by COX-2 inhibitor is readily apparent to any skilled artisan as well as other acute or chronic fatigues regardless of its pathologies where reasonable expectation of success would flow naturally from following the suggestion of the prior art.

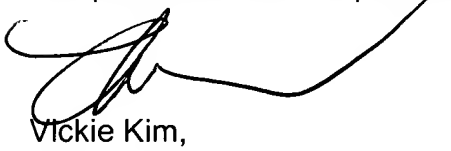
One would have been motivated to make such modification because COX-2 inhibitor's selective inhibitory activity would allow less undesirable side effect and is desirable than other non-steroidal anti-inflammatory drugs (NSAID) due to its therapeutic superiority. One would have been motivated to combine these references because the teachings are reasonably pertinent to the particular problem with which the applicant was concerned. Furthermore, it is always desired to have extended therapeutic modalities that would increase patient's compliance because patient's

selection would be made on individual's need and preference, which would eventually have improved the overall quality of the treatment and increase the industrial value.

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent Examiner
Art unit 1614